

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):

Julia E. Thompson, et al.

App. No.:

10/018,452

Conf. No.:

4408

Filing Date:

October 25, 2002

Title:

SPECIFIC BINDING ANTIBODIES

AND ANTIBODY FRAGMENTS

FOR TGFB₁

Art Unit:

1641

Examiner:

Not yet assigned.

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this

date: 04/20/05

Date

David W. Clough, Ph.D Registration No. 36,107

INFORMATION DISCLOSURE STATEMENT PURSUANT TO 37 C.F.R. §§ 1.56, 1.97 and 1.98

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In compliance with 37 C.F.R. § 1.97 and the continuing duty of disclosure under 37 C.F.R. § 1.56, Applicants call to the attention of the Examiner the references listed on the attached Forms PTO/SB/08A and PTO/SB/08B. It is respectfully requested that this Information Disclosure Statement be entered and the documents listed on attached Form PTO/SB/08A and PTO/SB/08B be considered by the Examiner and made of record.

In accordance with 37 C.F.R. § 1.97(g), this Information Disclosure Statement is not to be construed as a representation that a search has been made. In accordance with 37 C.F.R. § 1.97(h), this Information Disclosure Statement is not to be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in 37 C.F.R. § 1.56(b).

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Page 2

In accordance with 37 C.F.R. § 1.97(e)(1), Applicant hereby certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the present statement, as evidenced by the date of the enclosed search report.

No fees are believed to be due in connection with the filing of this Information Disclosure Statement, however, should any additional fees under 37 C.F.R. §§1.16 to 1.21 be deemed necessary for any reasons relating to this document, the Commissioner is hereby authorized to deduct the fees form Howrey Simon Arnold & White, LLP Deposit Account 08-3038 referencing docket number 05569.0006.PCUS00.

Respectfully submitted,

HOWREY SIMON ARNOLD & WHITE, LLP

By:

David W. Clough, Pl Registration No.: 36, NO.

Customer No.: 22930

April 20, 2005 HOWREY SIMON ARNOLD & WHITE, LLP 321 N. Clark Street, Suite 3400 Chicago, IL 60661 (312) 595-1239 (main) (312) 595-1408 (direct) (312) 595-2250 (fax)

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PE		titute for for	n 1449	A/PTO	Complete if Known		
	SINE	ODMATI	ON.	DISCLOSURE	Application Number	10/018,452	
2 5 20	D11	TEMEN'	T RV	APPLICANT	Filing Date	October 25, 2002	
7 3 44			ı	ATTENDENT	First Named Inventor	Julia E. Thompson, et al.	
	(use			,	Group Art Unit	1641	
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(AUE	Sheet	1	of	5	Attorney Docket Number	05569.0006.PCUS00	

		U.S. P	ATENT DOCU	MENTS	
Examiner Initials*	Cite No. 1	Document Number Number – Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A 1	5,262,319	11/16/1993	Iwata et al.	
	A2	5,824,297	10/20/1998	Iwata et al.	
	A3	5,871,724	2/16/1999	Iwata et al.	
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		FOREIGN	PATENT DO	CUMENTS		
		Foreign Patent Document			Pages, Columns,	
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Examiner Initials*	Cite No. 1	Country Code ³ –Number ⁴ – Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Passages or Relevant Figures Appear	T ⁶
	B1	WO 97/13844	04-17-1997	Julia E. Thompson et al.	100	
	B2	GB 2 305 921	04-23-1997	Julia E. Thompson et al.		
-	B3	WO 92/00330	01-09-1992	Kenneth K. Iwata et al.		
	B4	JP 06165692 (Abtract)	06-14-1994	Umeda Makoto, et al.		
	B5	JP 06165692 A (Abstract)	06-14-1994	Umeda Makoto, et al.		<u> </u>

Examiner	Date
Signature	Considered

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Applicant's unique citation designation number (optional). Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450. Alexandria, VA 27313-1450. 1450, Alexandria, VA 22313-1450.

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Sub	stitute for	form 1449	A/PTO	Complete if Known		
INII	EODM A	TION	DISCLOSURE	Application Number	10/018,452	
				Filing Date	October 25, 2002	
STATEMENT BY APPLICANT				First Named Inventor	Julia E. Thompson, et al.	
				Group Art Unit	1641	
(use	(use as many sheets as necessary)			Examiner Name	To be assigned	
Sheet	2	of	5	Attorney Docket Number	05569.0006.PCUS00	

		OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T ²
	C1	Supplemental Search Report of Corresponding European Application No. 04014972.6, dated December 12, 2004	
	C2	Burmester, James K., et al., "Mutational Analysis of a Transforming Growth Factor-β Receptor Binding Site," <i>Growth Factors</i> , <i>Harwood Academic Publishers</i> , Vol. 15, No. 3, 1998, pp. 231-242.	
	C3	Flanders, Kathleen, C., et al., "Antibodies to Peptide Determinants in Transforming Growth Factor β and Their Applications," <i>Biochemistry, American Chemical Society</i> , 1988, Vol. 27, 739-746.	
	C4	Hoefer, Magdalene, et al., "Anti-Transforming Growth Factor β) Antibodies With Predefined Specificity Inhibit Metastasis of Highly Tumorigenic Human Xenotransplants in nu/nu Mice," Cancer Immunology and Immunotherapy, Vol. 41, No. 5, 1995, 302-308.	
	C5	Su Wen Qian, et al., "Binding Affinity of Transforming Growth Factor-Beta for its Type II Receptor is Determined by the C-Terminal Region of the Molecule," <i>Journal of Biological Chemistry, American Society of Biological Chemists</i> , Vol. 271, No. 48, 29 November 1996, 30656-30662.	
	C6	R&D Systems Inc. Catalog, "Monoclonal Anti-human TGF-β1 Antibody", Catalog No. MAG240, June 20, 2000, pp. 1-2	
	C7	Oncogene Research Products, "Transforming Growth Factorβ1 (Ab-1) Monoclonal Antibody, Catalog No. GF33L.	
	C8	R&D Systems, Inc. Catalog, Monoclonal Anti-human TGF-β1 Antibody", Catalog No. MAB2401, January 30, 2002, pp. 1-2	
	C9	R&D Systems, Inc. Catalog, Monoclonal Anti-TGF-β2 Antibody", Catalog No. MAB612, June 28, 2001, pp. 1-2	
	C10		

Examiner	Date	
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Subs	stitute for	form 144	9A/PTO	Complete if Known		
INI	FODM.	ATION	DISCLOSURE	Application Number	10/018,452	
			APPLICANT	Filing Date	October 25, 2002	
512	AL IUIVII	EILI DI	AIIDICAN	First Named Inventor	Julia E. Thompson, et al.	
		_		Group Art Unit	1641	
(use	(use as many sheets as necessary)			Examiner Name	To be assigned	
Sheet	3	of	5	Attorney Docket Number	05569.0006.PCUS00	

	C11	R&D Systems, Inc. Catalog, Monoclonal Anti-TGF-β3 Antibody", Catalog No.	
		MAB643, June 21, 2001, pp. 1-2	
	C12	Data Specification Sheet - Chemicon International, Catalog No. MAB1032, "Mouse	
		Anti-Human Transforming Growth Factor (TGF) Monoclonal Antibody."	
	C13	Yes Biotech Laboratories, Ltd. Website homepage –	
		http://www.yesbiotech.com/index.html	
1	C14	Monoclonal Antibodies: Murine Anti-Human TGF β data sheet – Thursday, February	
		7, 2002, Yes Biotech Laboratories Ltd. Website:	
		http://www.yesbiotech.com/tech14.htm	
	C15	RDI – Research Diagnostics, Inc. Website homepage – Thursday, February 7, 2002; Quick	
		Access to Links for On Line Spec Sheets - http://www.researchd.com/index.htm	
	C16	"Cytokines, Growth Factors Chemokines: Antibodies: and Mouse Monoclonal Antibody to	
		Human TFG-β (October 3, 2001) - RDI – Research Diagnostics, Inc. Website homepage –	
		Thursday, February 7, 2002; Links for On Line Spec Sheets –	
		http://www.researchd.com/cytokines/lgfbab.htm	<u> </u>
	C17		
		http://www.SciQuest.com/cgi-	
		bin/ncommerce3/ExecMacro/product_details.d2w/report?Tmstmp=1013101956096&	
-		Refresh=N, Thursday, February 7, 2002	_
	C18	Catalog No. MO-C40009.D, Mouse Anti-Human TGFβ Monoclonal Antibody, Clone	
		Number: 2C6; Anogen/Yes Biotech Laboratories Ltd.; http://www.SciQuest.com/cgi-	
		bin/ncommerce3/ExecMacro/product_details.d2w/report?Tmstmp=1013102046067&;	
		Thursday, February 7, 2002	
	C19	Catalog No. MO-C40009.E, Mouse Anti-Human TGFβ Monoclonal Antibody, Clone	
		Number: 2E6; Anogen/Yes Biotech Laboratories Ltd.; http://www.SciQuest.com/cgi-	
		bin/ncommerce3/ExecMacro/product_details.d2w/report?Tmstmp=1013102046067&;	4
]		Thursday, February 7, 2002	
	C20	Catalog No. MO-C40009.F, Mouse Anti-Human TGFβ Monoclonal Antibody, Clone	
		Number: 8C4; Anogen/Yes Biotech Laboratories Ltd.; http://www.SciQuest.com/cgi-	
		bin/ncommerce3/ExecMacro/product_details.d2w/report?Tmstmp=1013102046067&;	
		Thursday, February 7, 2002	
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Sheet	4	of	5	Attorney Docket Number	05569.0006.PCUS00	

C21	Number: 4C2; Anogen/Yes Biotech Laboratories Ltd.; http://www.SciQuest.com/cgibin/ncommerce3/ExecMacro/product_details.d2w/report?Tmstmp=1013102046067&; Thursday, February 7, 2002	
C22	Oncogene Research Products website – Catalog No. GF16 – Transforming Grwoth Factorβ3 (Ab-1) Monoclonal Antibody, http://www.apoptosis.com/products/ProductDetail_ONC.asp?catNO=GF16, February 7, 2002.	
C23	ATCC, Welcome to the Monoclonal Connection (Hybridoma Data Bank) – What is the Hybridoma Data Bank (HDB), http://www/atcc:org/SearchCatalogs/hdb.cfm, pp. 1-2, February 7, 2002.	
C24	ATCC Search "TGFb" Catalog No. 1024236 Re: 1 G>Homo sapiens 1, CN>human an 1024236 – http://phage.atcc.org/cgi-bin/searchengine/hdb/Longview.cgl?view=/pub/textfiles/hdb-di.out.17906760&text=TGFb, February 7, 2002.	
C25	1024691 – http://phage.atcc.org/cgi- bin/searchengine/hdb/Longview.cgl?view=/pub/textfiles/hdb-di.out.17906760&text=TGFb, February 7, 2002	
C26	Abstract, Dasch, J. R., et al., "Monoclonal antibodies recognizing transforming growth factor-beta. Bioactivity neutralization and transforming growth factor beta 2 affinity purification," J. Immunol., 1989 Mar. 1:142(5):1536-41.	
C27	Abstract, Lucas, C., et al., "The autocrine production of transforming growth factorbeta 1 during lymphocyte activation. A study with a monoclonal antibody-based ELISA, <i>J. Immunol.</i> , 1990, Sep. 1:145(5):1415-22.	
C28	Abstract, Wojtowicz-Praga, S., et al., "Modulation of B16 melanoma growth and metastasis by anti-transforming growth factor beta antibody and interleukin-2," <i>J. Immunother. Emphasis Tumor Immunol.</i> , 1996 May; 19(3):169-75.	
C29	Abstract, Hoefer, M., et al., "Anti-(transforming growth factor beta) antibodies with predefined specificity inhibit metastasis of highly tumorigenic human xenotransplants in nu/nu mice," <i>Cancer Immunol. Immunother.</i> , 1995 Nov. 41(5):302-8.	

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Substitute for form 1449A/PTO				Complete if Known		
INI	ORMA	ATION I	DISCLOSURE	Application Number	10/018,452	
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(use as many sheets as necessary)			iecessary)	Examiner Name	To be assigned	
Sheet	5	of	5	Attorney Docket Number	05569.0006.PCUS00	

C30	transforming growth factor-beta1," Hybridoma, 12(4):441-53, 1993 Aug.				
C31	Lucas, Catherine, et al., "The Autocrine Production of Transforming Growth – Factorβ ₁ During Lymphocyte Activation," <i>The Journal of Immunology</i> , Vol. 145, 1415-1422, No. 5, September 1, 1990.				
C32	Tahara, N., et al., "Synthetic Peptide-Generated Monoclonal Antibodies to Transforming Growth Factor-β1," Hybridoma, Vol. 12, No. 4, 1993, 441-453.	-			
C33	Hoefer, Magdalene, et al., "Anti-(transforming growth factor β) antibodies with predefined specificity inhibit metastasis of highly tumorigenic human xenotransplants in nu/nu mice," <i>Cancer Immunol. Immunother.</i> , (1995) 41:302-308.				

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